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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,940	07/13/2001	Vincent Fischetti		3618

7590 09/30/2004  
New Horizons Diagnostics, Inc.  
9110 Red Branch Road  
Columbia, MD 21045-2014

EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/910,940

Applicant(s)

FISCHETTI ET AL.

Examiner

Allison M Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-129 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-129 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-60, 67-71, 74-75, 78-85, & 91-129, drawn to a method of preventing food poisoning in a food stock, classified in class 435, subclass 177.
- II. Claims 61-66, drawn to a method of preventing food poisoning on a surface, classified in class 422, subclass 1.
- III. Claims 72-73, drawn to a bacterial resistant animal feed, classified in class 426, subclass 635.
- IV. Claims 76-77, drawn to a bacterial resistant salad bar, classified in class 426, subclass 615.
- V. Claims 86-90, drawn to bacterial resistant ground beef, classified in class 426, subclass 574.

The inventions are distinct, each from the other because of the following reasons:

Inventions I is related to Inventions III, IV, and V as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make a variety of materially different products. Because the method of Invention I can be used to make any of the products of Inventions III, IV, or V, it is not specific for any one product, and therefore restriction is proper.

Inventions I and II are distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent on each other, not to be used together and have

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different functions, modes of operation, and effects. In the instant case the methods of Invention I involves food stock for consumption, and therefore must have considerations for safety and poison levels; the method of Invention II involves a surface, the same safety considerations do not need to be taken into account. Furthermore, Invention I requires the enzyme be produced by a bacteria infected with a bacteriophage, Invention II does not make any requirements on where the enzyme is obtained from.

Inventions III, IV, and V are distinct inventions and thus are subject to restriction. The inventions are distinct in that the products are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the different food types constitute distinct inventions because they are used and stored differently, undergo different treatments to be prepared for consumption, and therefore would be treated differently. For example, food for human consumption, such as salads and ground beef has very different health standards than animal feed. Further, salads and most animal feeds consist of plants and grains, intended to be eaten raw, ground beef, however, is animal meat, and is intended to be cooked. Plants and grains have very different bacterial considerations than raw meat, as raw meat, especially ground meat, is a breeding ground for bacteria. Therefore the products are distinct and restriction is proper.

Inventions II is distinct from Inventions III, IV, and V. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Invention II cannot be used to make the products of Inventions III, IV, or V. Inventions III, IV, and V are food stock; the method of Invention II is intended for surfaces only.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, dealing with both treatment methods and very distinct products, different classifications, and a search for one group does not require a search

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for another group, for example the searches for ground animal meat for human consumption does not overlap with sanitation of animal feed, and none overlap with surface cleaning. Therefore, restriction for examination purposes as indicated is proper.

Upon the election of Inventions I, elections of species is required from the following categories:

**Food Stock:** Claim 1 is generic to a plurality of disclosed patentably distinct species comprising livestock (election includes claims 2-8, and 67), eggs (election includes claims 48-52, and 91), salad (election includes claims 34-38, and 74), animal carcasses (election includes claims 39-47, 78, and 82), food to be canned (election includes claims 53 and 96), and liquids (election includes claim 113). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Enzyme:** Claims 1, 67, 74, 78, 82, 91, 96, 113 are generic to a plurality of disclosed patentably distinct species comprising lytic enzymes, shuffled lytic enzymes, chimeric lytic enzymes, and combinations thereof. For claims 74, 78, 82, 91, 96, and 113 the species holin enzymes is also included in this election. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Bacteria which Enzyme is Specific for:** Claim 1 is generic to a plurality of disclosed patentably distinct species comprising *Pseudomonas*, *Streptococcus pneumoniae*, *Streptococcus fasciae*, *Listeria*, *Salmonella*, *E. coli*, *Campylobacter*, *Streptococcus mutans*, *Mycobacterium tuberculosis*, and *Streptococcus* (Claims 10-20 and 88). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Type of Buffer:** Claim 23 is generic to a plurality of disclosed patentably distinct species comprising a buffer with a reducing agent (election includes claims 25 and 26), a buffer with a metal chelating reagent (election includes claims 27 and 28), and a citrate-phosphate buffer (claim 29).

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Type of Carrier:** Claims 9, 71, 75, 84, 92, 99, and 116 are generic to a plurality of disclosed patentably distinct species comprising water (found in claims 21, 36, 58, 58, and 95), oil (found in claims 21, 36, 85, and 95), micelles (found in claims 21, 37, 85, 95, and 113), inverted micelles (found in claims 21, 37, 85, and 95), reverse micelles (found in claims 21, 37, 100, and 117), liposomes (found in claims 21, 37, 85, 95, and 117), starches (found in claims 21, 85, and 95), carbohydrates (found in claims 21, 85, and 95), emulsions (found in claim 58), solutions (found in claim 58), and combinations thereof (found in claims 21, 37, 85, 95, and 117). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Protective Structure:** Claim 59 is generic to a plurality of disclosed patentably distinct species comprising micelles, liposomes, and inverted micelles. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Form of Administration:** Claim 1 is generic to a plurality of disclosed patentably distinct species comprising spraying (found in claims 35, 36, and 50), dusting (found in claims 38, 42, 81, and 94), liquid to be dipped in (found in claims 41, 49, 80, and 93), and powder (found in claims 46, 51, and 52). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the election of Inventions II, elections of species is required from the following categories:

**Enzyme:** Claim 61 is generic to a plurality of disclosed patentably distinct species comprising lytic enzymes (found in claims 61 and 62), shuffled lytic enzymes, chimeric lytic enzymes, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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**Carrier:** Claim 62 is generic to a plurality of disclosed patentably distinct species comprising emulsions, water, and a solution (found in claim 63). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the election of Inventions III, an election of species is required from the following category:

**Enzyme:** Claim 72 is generic to a plurality of disclosed patentably distinct species comprising lytic enzymes, shuffled lytic enzymes, chimeric lytic enzymes, holin enzymes, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the election of Inventions IV, an election of species is required from the following category:

**Enzyme:** Claim 76 is generic to a plurality of disclosed patentably distinct species comprising lytic enzymes, shuffled lytic enzymes, chimeric lytic enzymes, holin enzymes, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the election of Inventions V, an election of species is required from the following categories:

**Enzyme:** Claim 86 is generic to a plurality of disclosed patentably distinct species comprising lytic enzymes, shuffled lytic enzymes, chimeric lytic enzymes, holin enzymes, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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**Carrier:** Claim 89 is generic to a plurality of disclosed patentably distinct species comprising water, oil, micelles, inverted micelles, liposomes, starches, carbohydrates, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that any of the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

An election must be made in replying to this Office action. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

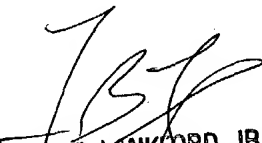
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained



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Allison M Ford  
Examiner  
Art Unit 1651

  
LEON B. LANKFORD, JR.  
PRIMARY EXAMINER